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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| MCGARRY, SEAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/836,073 | DASGUPTA ET AL. | |
| | Examiner | Art Unit | |
| | Sean R. McGarry | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9-12,20-24,36 and 37* is/are pending in the application.

4a) Of the above claim(s) *20-24* is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *1-7,9,10,12,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/1/02,12/8/03*. 3/21/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2005 has been entered.

Claims 1-7, 9, 11, and 12 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The grounds set forth for this rejection in the previous Official Action have been withdrawn in view of applicant's amendments to the claims and the arguments set forth in the papers filed 11/17/05.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 12, 3, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to require that $A^4$, $A^{12}$, and $A^{17}$ be independently E, D or Q. The claim formerly required $A^4$, $A^{12}$ and $A^{17}$ to be independently acidic amino acids.

Claim 1 has been amended to recite "A" at former position $A^5$, "I" at former position "$A^7$", "C" at former position "$A^8$", "I" at former position "$A^{11}$", and "G" at former position"A16". The original claims defined these positions as representing any amino acid.

Claim 1 has been amended to recite "Q" at former position "$A^{10}$". This position was formerly defined as representing a basic or polar neutral amino acid.

Claim 1 has been amended to recite specific amino acids at former positions "$A^{13, 15 \text{ and } 18}$". The positions were formerly defined as being independently aromatic amino acids.

Claim 7 has been amended to recited only $A^{14}$ being phenylalanine or tyrosine. No support could be found for this limitation outside the context of also including $A^{13, 15 \text{ and } 18}$.

Claim 9 has been amended similarly as claim 7 and suffers the same issues.

All the above taken as a whole in the new formula of claim 1 constitutes new matter. The formula of Claim 1 now represents a subgenus not identified in the specification of claims in the specification as filed. The specification does not clearly point one to the specific subgenus now recited. It is not readily apparent from the original claims or the specification as filed that there is support for the subgenus now recited.

Claim 1 has been amended to recite a negative proviso that the formula of claim 1 does not include SEQ ID NO: 13 when all amino acids are in the L-form. No support for this specific limitation could be found in the specification as filed. It is not readily apparent from the original claims or the specification as filed that there is support for the limitation now recited.

New claim 36 differs from claim 1 only in so far as it does not provide for Q at positions $A^4$, $A^{12}$, and $A^{17}$.

Applicant's arguments filed 11/17/05 have been fully considered but they are not persuasive.

Applicant traverses the above rejection asserting that one in the art would be "reasonably led" to the particular sub genus now claimed [it is noted that applicant uses the term "species" instead of "sub genus", however, the particular species claimed, i.e. those in claims 10 and 11, are not and have not been rejected under the above grounds]. Applicant asserts that the examiner has not fulfilled the burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the disclosure a description of the invention now claimed as required by MPEP 2163.04. The

context of 2163.04 relied upon by applicant is supplied below. It is noted that the burden on the examiner is on the disclosure as filed. The disclosure in the instant case is NOT as filed , but as amended. The examiners actions were proper since applicant provided no specific support for the changes made in the claims. See the relevant portion of MPEP 2163.04 (I)(B) below.

2163.04 Burden on the Examiner with Regard to the Written Description Requirement

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97.

2163.04(I)(B):

Establish a prima facie case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the

application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description. A simple statement such as "Applicant has not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitation ____' in the application as filed." may be sufficient where the claim is a new or amended claim, the support for the limitation is not apparent, and applicant has not pointed out where the limitation is supported.

It is not agreed that one in the art would be reasonably led to the sub generic formula now recited in claim 1. Applicant has argued for support for each of the individual changes made in the original formula I to make the new sub generic formula instantly recited in amended claim 1. Applicant essentially argues for each of the individual changes, that the changes has been identified as a preferred embodiment or that "nearly every example in Table 1 provides support for each particular change in formula I. However, when taken as a whole the changes to formula in claim 1 now actually excludes 13 of the 18 distinct sequences of Table 1. When one looks to Table 2, there are species of Table 1 that meet the structural limitations of claim 1, yet do not have the desired activity of viral inhibition [701]. It is also noted that the specification, as filed, **requires** [paragraph 14] A4, $A^{12}$, and $A^{17}$ to be to acidic amino acids. To have Q at any of $A^4$, $A^{12}$, or $A^{17}$ location is simply contrary to the specification and would clearly not be a species one in the art would have been reasonably led by the specification. Applicant points to peptide 701 as support for Q at the position A12, but it is certainly unclear how applicant could rely on an example that is clearly set outside and excluded from the

invention by the specification as filed [see paragraph 14]. Further it is not clear from the specification as filed that, in the context of the formula in claim 36, there is any support for A14 **not** being an aromatic amino acid since the specification only indicates, in the context of the original formula of claim 1 as filed, that in "certain embodiments" A14 can be neutral polar where there is no indication that such embodiments where described or disclosed in the application as filed in the context of the formula of the instant claim 1 or 36. It appears that applicant, with the introduction of the formula in the instant claim 1 and 36, now attempts to define the hereunto-undefined "certain embodiments".

Applicant argues that the proviso in claim 1 and 36 is not new matter since paragraph [22] of the specification indicates that applicant did not intend to exclude the d-form. This is not convincing. First, it appears that the specification indicates that the LAP peptide is excluded [paragraph 04] from the invention and since paragraph 22 is drawn to peptides of the invention it would appear to be new matter to now include some part of what was wholly indicated to not be a part of the invention. Further ther is certainly no support for the specific exclusion of a particular peptide form from the subgenus now claimed.

Claims 1-7 and 9, 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides of formula (1) that comprise E at $A^4$, A at $A^6$, I at $A^7$, C at $A^8$, Q at $A^{10}$ I at $A^{11}$, E at $A^{12}$, Y at $A^{13}$, F at $A^{15}$, G at $A^{16}$, D at $A^{17}$, F at $A^{18}$ does not reasonably provide enablement for the full scope of formula (1). The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is maintained for the same reasons of record.

The instant invention is drawn to the use of peptides based on LAP, which inhibits viral replication. The instant claims are broadly drawn to peptides embraced within formula (1) and also includes specific peptides in claims 11 and 10, for example. Applicant has shown in Table 1, that peptides based on LAP that comprises E at $A^4$, A at $A^6$, I at $A^7$, C at $A^8$, Q at $A^{10}$ I at $A^{11}$, E at $A^{12}$, Y at $A^{13}$, F at $A^{15}$, G at $A^{16}$, D at $A^{17}$, F at $A^{18}$ function to inhibit viral replication. Table 1 show that those that do not comprise these specific amino acid residues at these positions do not work as viral inhibitors. Table I shows that the specifically claimed SEQ ID NO: 3 (701) did not have viral inhibitory properties. It does not appear based on applicants disclosure that one in the art would expect that peptide that are embraced within the broad formula (1) would be expected to have antiviral properties since it has been shown that only those with E at $A^4$, A at $A^6$, I at $A^7$, C at $A^8$, Q at $A^{10}$ I at $A^{11}$, E at $A^{12}$, Y at $A^{13}$, F at $A^{15}$, G at $A^{16}$, D at $A^{17}$, F at $A^{18}$ show inhibitory properties. The specification does not provide any other use for the peptides within formula (1) other than as viral inhibitors. One in the art therefor would not know what to use those peptides embraced within formula (1) that do not have inhibitory properties, for example. One in the art would not know how to use 701, for example. Claim 11 comprises specific sequences that do not contain E at $A^4$, A at $A^6$, I at $A^7$, C at $A^8$, Q at $A^{10}$ I at $A^{11}$, E at $A^{12}$, Y at $A^{13}$, F at $A^{15}$, G at $A^{16}$, D at $A^{17}$, F at $A^{18}$ and based on the instant specification (Table 1) and would therefore not be expected to have those antiviral properties associated with LAP, for example. The structure of Formula (1) has not been demonstrated to correlate with the asserted activity of viral inhibition. One

in the art would be required to perform undue experimentation to practice the instant invention since one would be required to perform undue trial and error experimentation to determine what particular uses those species within formula (1) have that do not possess antiviral properties, for example.

Applicants arguments filed have been considered but they are not sufficient to overcome the rejection of record. Applicant asserts that the claims have been narrowed and that SEQ ID NO: 3 should not be included in the rejection. Applicant offers no specific arguments as to how the rejection of record is improper. SEQ ID NO: 3 is believed to be correctly included in the rejection of record since the invention is drawn to antivirals and SEQ ID NO: 3 has simply been shown in the specification not to have antiviral capacity. Applicant asserts that SEQ ID NO: 3 could be used to deliver some other compound to the liver, for example. The specification provides no guidance for such methods other than the mere statement. Furthermore, it would appear that SEQ ID NO: 3 is outside the teachings of the invention since paragraph 14 of the specification requires an acidic amino acid at position 12 of which SEQ ID NO: 3 does not have. It is unclear how the specification as filed would enable a compound that has been defined by the specification as filed to be excluded from the invention? The contradictory requirements of the specification and that which is now claimed and argued would leave one in the art at a loss as to how to use embodiments such as SEQ ID NO: 3 since they are at the same time claimed but specifically excluded by the specification.

Claim 11 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635